

K 091495

Pg 1064

SEP - 8 2009

510(k) SUMMARY

Single Use 3-Lumen Extraction Balloon V B-V233P-A, B-V233P-B, B-V433P-A, B-V433P-B B-V243Q-A, B-V243Q-B, B-V443Q-A, B-V443Q-B

1 General Information

- **Applicant:** OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
Establishment Registration No: 8010047
- **Official Correspondent:** Stacy Abbatiello Kluesner, M.S., RAC
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 484-896-5405
FAX: 484-896-7128
Email: stacy.kluesner@olympus.com
- **Manufacturer** Aomori Olympus Co., Ltd.
2-248-1 Okkonoki, Kuroishi-shi,
Aomori, Japan, 036-0367
Establishment Registration No.: 9614641

2 Device Identification

- **Device Trade Name** Single Use 3-Lumen Extraction Balloon V
B-V233P-A, B-V233P-B, B-V433P-A, B-V433P-B,
B-V243Q-A, B-V243Q-B, B-V443Q-A, B-V443Q-B
- **Common Name** 3-Lumen Extraction Balloon
- **Regulation Number** 21 CFR 876. 5010
- **Regulation Name** Biliary catheter and accessories
- **Regulatory Class** II
- **Classification Panel** Catheter, Biliary, Diagnostic/Biliary Stone Dislodger
Endoscope and/or Accessories
- **Product Code** FGE/LQR/KOG

3 Predicate Device Information

- Device Name: Single Use 3-Lumen Balloon Catheter B-230Q-A, B-230Q-B
- Common Name: Balloon Catheter
- Manufacturer: Aomori Olympus Optical Co., Ltd.
- 510(k) No. K033333 ✓

4 Device Description

The Single Use 3-Lumen Extraction Balloon V, model B-V233P-A, B-V233P-B, B-V433P-A, B-V433P-B, B-V243Q-A, B-V243Q-B, B-V443Q-A and B-V443Q-B is a balloon catheter, included three kinds of premeasured syringe, to endoscopically remove stones such as calculi, pancreatic and common bile duct stones, to remove bile sludge from the biliary system and to facilitate injection of contrast medium into the biliary system.

The details of the line up of this subject devices are showed in the below.

	B-V233P -A	B-V233P -B	B-V433P -A	B-V433P -B	B-V243Q -A	B-V243Q -B	B-V443Q -A	B-V443Q -B
Guidewire port structure	Over the wire type	Over the wire type	Over the wire type	Over the wire type	Distal Wireguided type	Distal Wireguided type	Distal Wireguided type	Distal Wireguided type
Injection outlet location type	Above the balloon	Below the balloon	Above the balloon	Below the balloon	Above the balloon	Below the balloon	Above the balloon	Below the balloon
Maximum diameter of the balloon (mm)	φ 15	φ 15	φ 20	φ 20	φ 15	φ 15	φ 20	φ 20

5 Indications for Use

These instruments have been designed to be used with Olympus endoscopes to endoscopically remove stones such as calculi, pancreatic and common bile duct stones, to remove bile sludge from the biliary system and to facilitate injection of contrast medium into the biliary system

6 Comparison of Technological Characteristics

The Single Use 3-Lumen Extraction Balloon V, model B-V233P-A, B-V233P-B, B-V433P-A, B-V433P-B, B-V243Q-A, B-V243Q-B, B-V443Q-A and B-V443Q-B is identical to the predicate device in intended use, and similar in specifications except for the change of the guidewire port structure and expansion of the maximum diameter of the balloon. Comparison between the subject and predicate devices is shown in Table 1.

K091495
Pg 3 of 4

Table 1. Comparison of Specifications

Subject Device:

B-V233P-A, B-V233P-B, B-V433P-A, B-V433P-B
B-V243Q-A, B-V243Q-B, B-V443Q-A, B-V443Q-B

	B-V233P-A B-V233P-B	B-V433P-A B-V433P-B	PD: #K033333 B233Q-A B-233Q-B
Maximum diameter of the balloon	φ 15mm	φ 20mm	φ 15mm (φ 20mm is cleared a 510(k) in #K063677)
Maximum outer diameter of the sheath	φ 2.7mm	φ 3.2mm	φ 2.55mm
Compatible channel diameter	φ 2.8mm or larger	φ 3.2mm or larger	φ 2.8mm or larger
Working length	1900mm		1950mm
Structure for attaching to endoscope (Hook)	Provided		Not provided
Guidewire port structure	Over the wire type		Over the wire type
Pre-measured syringes in different sizes for inflation	1.1mL (φ 8.5mm) 1.8mL (φ 11.5mm) 3.4mL (φ 15mm)	2.4mL (φ 15mm) 4.0mL (φ 18mm) 5.6mL (φ 20mm)	1.2mL (φ 8.5mm) 2.0mL (φ 11.5mm) 3.8mL (φ 15mm)

	B-V243Q-A B-V243Q-B	B-V443Q-A B-V443Q-B	PD: #K033333 B233Q-A B-233Q-B
Maximum diameter of the balloon	φ 15mm	φ 20mm	φ 15mm (φ 20mm is cleared a 510(k) in #K063677)
Maximum outer diameter of the sheath	φ 2.9mm	φ 3.2mm	φ 2.55mm
Compatible channel diameter	φ 3.2mm or larger		φ 2.8mm or larger
Working length	1950mm		1950mm
Structure for attaching to endoscope (Hook)	Provided		Not provided
Guidewire port structure	Monorail type		Over the wire type
Pre-measured syringes in different sizes for inflation	1.1mL (φ 8.5mm) 1.8mL (φ 11.5mm) 3.4mL (φ 15mm)	2.4mL (φ 15mm) 4.0mL (φ 18mm) 5.6mL (φ 20mm)	Unknown

K091495

pg 4 of 4

7 Conclusion

When compared to the predicate device, the single use 3-lumen extraction balloon V, model B-V233P-A, B-V233P-B, B-V433P-A, B-V433P-B, B-V243Q-A, B-V243Q-B, B-V443Q-A and B-V443Q-B does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OLYMPUS MEDICAL SYSTEMS CORP.
% Stacy Abbatiello Kluesner, M.S., RAC
Project Manager
Olympus America, Inc.
3500 Corporate Parkway
CENTER VALLEY PA 18034-0610

SEP - 8 2009

Re: K091495

Trade/Device Name: Single Use 3-Lumen Extraction Balloon V
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: LQR & FGE
Dated: July 31, 2009
Received: August 4, 2009

Dear Ms. Kluesner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

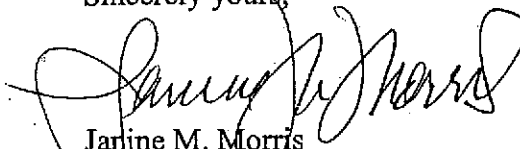
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/indr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jarine M. Morris", is written over the typed name.

Jarine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~K091459~~ K091495

Device Name: Single Use 3-Lumen Extraction Balloon V
B-V233P-A, B-V233P-B, B-V433P-A, B-V433P-B,
B-V243Q-A, B-V243Q-B, B-V443Q-A, B-V443Q-B

Indications For Use:

These instruments have been designed to be used with Olympus endoscopes to endoscopically remove stones such as calculi, pancreatic and common bile duct stones, to remove bile sludge from the biliary system and to facilitate injection of contrast medium into the biliary system.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

~~K091459~~ K091495